REMARKS

Claims 52-85, 94 and 100-113 presently appear in this case. Claims 65-75 have been allowed. The remaining claims have been rejected. The official action of March 11, 2005, has now been carefully studied. Reconsideration and allowance are hereby respectfully urged.

Briefly, the present invention relates to peptides derived from a domain that forms the central turn of a pyrogenic exotoxin, which peptide does not have toxin agonist activity and is capable of antagonizing toxin-mediated activation of T-lymphocytes.

Claims 88-99 have been rejected under 35 U.S.C. §112, first paragraph, as failing to comply with the written description requirement thereof, i.e., in the nature of new matter rejection. The examiner states that not a single one of SEQ ID NOs:13-18 require motifs KK and QELD. Thus, the examiner considers each of these SEQ ID NOs to be new matter. The examiner states that this new matter rejection is relevant to the computer and the paper copy of the Sequence Listing. This rejection is respectfully traversed.

Claims 88-99 (except for claim 94) have now been deleted, thus obviating this rejection. New claim 103 has now been added in place thereof. Previously appearing SEQ ID NOs:13-18 have now been deleted from the paper and the

computer-readable forms of the Sequence Listing, and new SEQ ID NOs:13, 14 and 15 have been added, as set forth in claim 103. Applicants have added into the present specification a new paper copy Sequence Listing section according to 37 C.F.R. §1.821(c) as new pages 1-5. Furthermore, attached hereto is a 3 1/2" disk containing the "Sequence Listing" in computer readable form in accordance with 37 C.F.R. §1.821(e).

The following statement is provided to meet the requirements of 37 C.F.R. §1.821(f) and 1.821(g) §1.825(a) and 1.825(b).

I hereby state, in accordance with 37 C.F.R. §1.825(a), that the amendments included in the substitute sheets of the sequence listing are believed to be supported in the application as filed and that the substitute sheets of the sequence listing are not believed to include new matter.

I hereby further state, in accordance with 37 C.F.R. §1.825(b), that the attached copy of the computer readable form is the same as the attached substitute paper copy of the sequence listing.

Under U.S. rules, each sequence must be classified in <213> as an "Artificial Sequence", a sequence of "Unknown" origin, or a sequence originating in a particular organism, identified by its scientific name.

Neither the rules nor the MPEP clarify the nature of the relationship which must exist between a listed sequence and an organism for that organism to be identified as the origin of the sequence under <213>.

Hence, counsel may choose to identify a listed sequence as associated with a particular organism even though that sequence does not occur in nature by itself in that organism (it may be, e.g., an epitopic fragment of a naturally occurring protein, or a cDNA of a naturally occurring mRNA, or even a substitution mutant of a naturally occurring sequence). Hence, the identification of an organism in <213> should not be construed as an admission that the sequence *per se* occurs in nature in said organism.

Similarly, designation of a sequence as "artificial" should not be construed as a representation that the sequence has no association with any organism. For example, a primer or probe may be designated as "artificial" even though it is necessarily complementary to some target sequence, which may occur in nature. Or an "artificial" sequence may be a substitution mutant of a natural sequence, or a chimera of two or more natural sequences, or a cDNA (i.e., intron-free sequence) corresponding to an intron-containing gene, or otherwise a fragment of a natural sequence.

The examiner should be able to judge the relationship of the enumerated sequences to natural sequences by giving full consideration to the specification, the art cited therein, any further art cited in an IDS, and the results of his or her sequence search against a database containing known natural sequences.

In new claim 103, SEQ ID NOs:13 and 14 both include the KK and QELD motifs that are disclosed as being important at page 26, lines 6-9 of the present specification. SEQ ID NO:13 is a decamer, such as the preferred compositions of SEQ ID NOs:3 and 4 in the present specification, and SEQ ID NO:14 is a dodecamer, such as the preferred compositions of SEQ ID NOs:1 and 2 of the present specification. The important conserved amino acids as stated in the specification remain in this consensus sequence and paragraph a) of claim 103 requires that the peptide does not have toxin agonist activity and is capable of antagonizing toxin-mediated activation of T-lymphocytes. Thus, the Xaa's must be filled with residues that permit this activity. As to SEQ ID NO:15, this is supported in the sentence bridging pages 25 and 26 of the present specification, which points out that residues 150, 152, 159 and 161 of SEB are conserved among along all staphylococcal enterotoxins. However, the present specification indicates that a substitution of Tyr for the Thr

at position 150 also produces good results. Accordingly, SEQ ID NO:15 is the consensus sequence with the four residues disclosed as being important in the paragraph bridging pages 25 and 26, modified to permit Tyr at position 150, as is present in SEQ ID NO:2. See Table 4 at page 56 of the present specification.

Accordingly, it is urged that new claim 103 contains no new matter for the same reasons that new paper copy and computer-readable form sequences contain no new matter. Reconsideration and withdrawal of this rejection are, therefore, respectfully urged.

Claims 50-64 and 76-87 have been rejected under 35 U.S.C. §102(b) as being anticipated by Tice. The examiner states that no recitation of "consisting of" amino acids 141-172 of SEB is found and, consequently, the claim is not limited to this length of a peptide. The examiner considers the long protein of Tice to fall within the "homologous" language of claim 50. This rejection is respectfully traversed.

Claim 50 has now been deleted in favor of new claim 100, which does not use the "homologous to" language. In claim 100 a), the peptide consists of a peptide that starts within or immediately after β-strand 7 and ends with α-helix 6 ("immediately after" was added to ensure that the preferred

peptide of SEQ ID NO:3 was covered). Thus, the peptide of claim 100 must be substantially shorter than that disclosed by Tice and is not anticipated by Tice. The peptides of new claim 103 are also substantially shorter than those disclosed by Tice. Accordingly, none of the present claims can be anticipated by Tice. Reconsideration and withdrawal of this rejection are respectfully urged.

It is submitted that all of the claims now present in the case clearly define over the references of record and fully comply with 35 U.S.C. §112. Reconsideration and allowance are, therefore, earnestly solicited.

Respectfully submitted,

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